

K 060232.....

Page 1 of 2**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS IN  
ACCORDANCE WITH SMDA OF 1990**

JUL 12 2006

DATE OF APPLICATION: 2006-01-25

Submitted by: TroKamed GmbH  
Kleine Breite 17  
78187 Geisingen  
Germany  
Tel.: +49 (0)7704/9244-0  
Fax: +49 (0) 7704/9244-44  
E-Mail: info@trokamed.de  
Homepage: www.trokamed.de

**1. DEVICE DESCRIPTION**

Trade Name: electrosurgical instruments and accessories  
Common Name: electrosurgical instruments and accessories

**2. CLASSIFICATION**

<b>Device:</b>	Electrosurgical cutting and coagulation device and accessories
<b>Panel:</b>	878 General and Plastic surgery
<b>Product Code:</b>	GEI
<b>Device Class:</b>	2
<b>Regulation Number:</b>	878.4400

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### 3. INTENDED USE

The Trokamed GmbH Resectoscope & Accessories are indicated for the resection of prostate tissue. The Trokamed GmbH Monopolar Electrodes are intended for use in minimal invasive techniques where unipolar electrosurgical cutting and coagulation are normally used.

The Trokamed GmbH Bipolar Electrodes are intended for use in minimal invasive techniques where bipolar electrosurgical cutting and coagulation are normally used.

The instruments are reusable; they are intended to be cleaned, sterilized and reused.

### 4. SUBSTANTIAL EQUIVALENCE

Manufacturer	510(k) Number	Device name
A Richard Wolf	K 973341	Unipolar electrodes
B Valleylab	K 964602	Valleylab coated electrodes
C Megadyne	K 040699	Leris
D Bissinger	K042077	BiTech Bipolar Scissors
E Karl Storz	K960757	Karl Storz Ureter Resectoscope
F COMEG Endoscopy	K 971881	Comeg Resectoscope and...

### 5. BIOCOMPATIBILITY

The biocompatibility has been approved based on ISO 10993 parts one, five and ten by the accredited Laboratory Bioservice.

### 6. STERILIZATION BY USER

Trokamed GmbH delivers all unipolar electrodes in Non-Sterile conditions. The user may sterilize these devices by using a validated and applicable sterilization process.

Trokamed GmbH recommends to use a steam-sterilizer that uses a validated sterilization cycle of 134°C / 270°F, 3 bar, for 10 minutes.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Trokamed GmbH  
% Karlheinz Trondle  
General Manager  
Kleine Breite 17  
78187 Geisingen  
Germany

**JUL 12 2006**

Re: K060232

Trade/Device Name: Electrosurgical instruments and accessories  
Regulation Number: 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulation Class: II  
Product Code: GEI  
Dated: June 26, 2006  
Received: June 28, 2006

Dear Mr. Trondle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

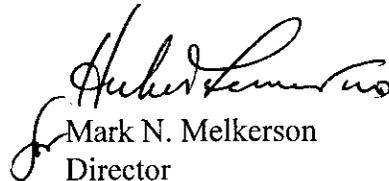
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Karlheinz Trondle

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K060232

**Indications for Use**

510(k) Number (if known): K060232

Device Name: Electrosurgical instruments and accessories

Indications For Use:

The Trokamed GmbH Resectoscope & accessories are indicated for the resection of prostate tissue.  
The Trokamed GmbH Monopolar Electrodes are intended for use in minimal invasive techniques where unipolar electrosurgical cutting and coagulation are normally used.  
The Trokamed GmbH Bipolar Electrodes are intended for use in minimal invasive techniques where bipolar electrosurgical cutting and coagulation are normally used.

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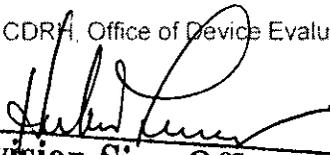
Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRA, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

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